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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,875	10/12/2000	Michifumi Tanga	TANGA2	5274

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BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 10/28/2002

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/601,875

Applicant(s)

TANGA ET AL.

Examiner

BJ Forman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-11, 13-16 and 22-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-11,13-16 and 22-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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FINAL ACTION

1. This action is in response to papers filed 20 August 2002 in Paper No. 19 in which claims 1,4 and 13 were amended and claim 3 was canceled. All of the amendments have been thoroughly reviewed and entered. The previous rejections of Claims 1, 2, 4-11, 13-15 and 22-25 in the Office Action of Paper No. 18 dated 29 March 2002 are withdrawn in view of the amendments. The previous rejection of Claim 16 is maintained. All of the arguments addressing Claims 1, 2, 4-11, 13-15 and 22-25 have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection.

Applicant has submitted no arguments regarding the art rejections of Claim 16.

New grounds for rejection are discussed.

The examiner's Art Unit has changed from 1655 to 1634. Please address future correspondence to Art Unit 1634.

Currently claims 1, 2, 4-11, 13-16 and 22-25 are under prosecution.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1),

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(2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Chrisey et al (U.S. Patent No. 5,688,742, issued 18 November 1997).

Regarding Claim 16, Chrisey et al disclose a chip for amplifying and immobilizing DNA (Column 9, lines 9-27).

The recitation "for amplifying and immobilizing DNA" is functional language and does not describe the claimed substrate in terms of structure. The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

"[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP, 2114). Because "for amplifying and immobilizing DNA" does not describe structural components of the claimed substrate, the recitation does not distinguish the substrate over the prior art substrate.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject

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matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 2, 4, 5, 9-11, 13-15 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chrisey et al (U.S. Patent No. 5,688,742, issued 18 November 1997) as defined by Sumiya et al (U.S. Patent No. 5,332,629, issued 26 July 1994) in view of Fodor et al (U.S. Patent No. 5,800,992, issued 1 September 1998).

Regarding Claim 1, Chrisey et al teach a solid state substrate for DNA immobilization (i.e. diamond) (Column 7, lines 24-28), wherein said substrate has a thermal conductivity ration of at least $0.1\text{W/cm}^{\circ}\text{K}$ as defined by Sumiya et al (Column 1, Table 1) wherein the surface of the substrate is modified by binding a chloride or hydroxyl radical (Column 7, lines 35-50) and wherein said substrate is used for immobilizing and amplifying DNA (Column 9, lines 22-27). Chrisey et al do not teach the surface of the substrate is roughened. However, substrates having a roughened surface were well known in the art at the time the claimed invention was made as taught by Fodor et al (Column 37, line 65-Column 38, line 6). Specifically, Fodor et al teach a similar substrate for DNA immobilization wherein the substrate is modified by binding a hydroxyl radical (Column 37, lines 42-64 and Columns 43-44) and wherein the surface of the substrate is roughened (i.e. machined or etched) thereby increasing the surface area and increasing the density of reagent attachment (Column 37, line 65-Column 38, line 6). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the substrate surface of Chrisey et al by roughening the surface as taught by Fodor et al to thereby increase surface area of the substrate for the obvious benefits of increasing the density of reagent attachment and reagent-binding as taught by Fodor et al (Column 37, line 65-Column 38, line 6).

The recitation "for amplifying DNA" in the preamble of Claim 1 and the recitation "for amplifying and immobilizing DNA" in lines 3-4 of Claim 1 are recitations of intended use for the claimed substrate. The courts have stated that a claim containing a "recitation with respect to

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the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). The intended use of the claimed substrate does not differentiate the claimed apparatus over the substrate of Chrisey et al.

Regarding Claim 2, Chrisey et al teach said substrate is diamond (Column 7, lines 24-28).

Regarding Claim 4, Chrisey et al teach said substrate has a polar radical at a terminal on the surface of the substrate (Column 7, lines 35-50 and Fig. 4-5).

Regarding Claim 5, Chrisey et al teach said substrate wherein said polar radical is hydroxyl radical, epoxy radical or amino radical (Column 7, lines 35-50).

Regarding Claim 9, Chrisey et al teach said substrate wherein said polar radical is an epoxy radical and said epoxy radical is introduced to a surface of said substrate with a silane coupling agent (Column 7, lines 41-43).

Regarding Claim 10, Chrisey et al teach said substrate wherein said polar radical is an amino radical and said amino radical is introduced to a surface of said substrate with a silane coupling agent (Column 7, lines 45-51).

Regarding Claim 11, Chrisey et al teach said chip wherein DNA is immobilized to said substrate (Column 3, lines 20-25 and Column 7, lines 21-28).

Regarding Claim 13, Chrisey et al teach a solid state substrate having DNA immobilized thereon wherein said substrate is diamond and is chemically modified by binding a chloride or hydroxyl radical (Column 7, lines 21-50) and wherein said substrate is used for immobilizing and amplifying DNA (Column 9, lines 22-27). Chrisey et al do not teach the surface of the substrate is roughened. However, substrates having a roughened surface were well known in the art at the time the claimed invention was made as taught by Fodor et al (Column 37, line 65-Column 38, line 6). Specifically, Fodor et al teach a similar substrate for

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DNA immobilization wherein the substrate is modified by binding a hydroxyl radical (Column 37, lines 42-64 and Columns 43-44) and wherein the surface of the substrate is roughened (i.e. machined or etched) thereby increasing the surface area and increasing the density of reagent attachment (Column 37, line 65-Column 38, line 6). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the substrate surface of Chrisey et al by roughening the surface as taught by Fodor et al to thereby increase surface area of the substrate for the obvious benefits of increasing the density of reagent attachment and reagent-binding as taught by Fodor et al (Column 37, line 65-Column 38, line 6).

Regarding Claim 14, Chrisey et al teach said substrate having DNA immobilized thereon wherein said substrate has a polar radical at a terminal of the surface of the substrate (Column 7, lines 41-50).

Regarding Claim 15, Chrisey et al teach said substrate wherein said polar radical is hydroxyl radical, epoxy radical or amino radical (Column 7, lines 35-50).

Regarding Claim 25, Chrisey et al teach the substrate of Claim 15 wherein said polar radical is an epoxy radical and said epoxy radical is introduced to a surface of said substrate with a silane coupling agent (Column 7, lines 41-43).

Response to Arguments

6. Applicant's arguments have been considered but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection.

7. Claims 6-8 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chrisey et al (U.S. Patent No. 5,688,642, issued 18 November 1997) as defined by Sumiya et al (U.S. Patent No. 5,332,629, issued 26 July 1994) in view of Fodor et al (U.S. Patent No. 5,800,992, issued 1 September 1998) as applied to Claims 5 and 15 above and further

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in view of Kobashi (U.S. Patent No. 5,77,372, issued 7 July 1998).

Regarding Claims 6-8 and 22-24, Chrisey et al teach a solid state substrate for DNA immobilization (i.e. diamond) (Column 7, lines 24-28), wherein said substrate has a thermal conductivity ration of at least $0.1\text{W}/\text{cm}^\circ\text{K}$ as defined by Sumiya et al (Column 1, Table 1) wherein said substrate is used for immobilizing and amplifying DNA (Column 9, lines 22-27) wherein said substrate is diamond (Column 7, lines 24-28) wherein said substrate is chemically modified by binding a hydroxyl radical to the substrate (Column 7, lines 41-50) wherein said substrate has a polar radical at a terminal on the surface of the substrate (Column 7, lines 35-50 and Fig. 4-5) and wherein said polar radical is hydroxyl radical, epoxy radical or amino radical wherein the polar radical is connected on a surface through an ester linkage, an amide linkage or introduced with a silane coupling agent (Column 7, lines 35-50). Fodor et al teach a similar substrate wherein the surface is roughened and they teach a motivation to roughen the surface i.e. increases surface area to thereby increase density of reagent binding (Column 37, lines 42-64 and Columns 43-44). Chrisey et al and Fodor et al do not teach said polar radical is a carboxyl radical. However, Kobashi teaches a similar a solid state substrate wherein said substrate is chemically modified to have a polar radical at a terminal wherein the polar radical is selected from the group consisting of hydroxyl, carboxyl, epoxy and amino (Column 10, line 63-Column 11, line 11). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the chemical modification of substrates as taught by Chrisey et al and Fodor et al by chemically modifying with a carboxyl radical as taught by Kobashi based on the teaching of Kobashi wherein hydroxyl, carboxyl, epoxy and amino radicals function equally as chemical modifiers for diamond surfaces (Column 11, lines 4-11). The courts have stated with regard to chemical homologs that the greater the physical and chemical similarities between the claimed species and any species disclosed in the prior art, the greater the expectation that the claimed subject matter will function in an equivalent manner (see *Dillon*, 99 F.2d at 696, 16 USPQ2d at 1904).

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Therefore, one of skill in the art would be motivated to chemically modify the substrate of Chrisey et al with a carboxyl radical based on the similar chemical and physical properties of polar radicals taught by Kobashi (Column 10, line 63-Column 11, line 11) because one skilled in the art would have expected the carboxyl radical to function in an equivalent manner.

Additionally, the skilled practitioner would have been motivated to the diamond substrate of Chrisey et al with a carboxyl radical based on the teaching of Kobashi wherein a biomolecule is immobilized via carboxyl radical-modification of diamond substrate (Kobashi, Column 10, line 63-Column 11, line 11).

Response to Arguments

8. Applicant argues that because Kobashi is not concerned with binding nucleic acids to their substrate and therefore there would be no motivation to combine the teaching of Chrisey et al with that of Kobashi. The argument has been considered but is not found persuasive for several reasons. First, Kobashi teaches attachment of bioidentifiers to their diamond substrate (Abstract) and teach the bioidentifiers are "long chain molecules". While they do not specifically teach that their bioidentifiers are nucleic acids, they do not define bioidentifiers and they especially do not teach the bioidentifiers are not nucleic acid. Second, while Kobashi does not teach that their bioidentifier are nucleic acids, nucleic acids are known as bioidentifiers because they identify their biomolecules e.g. complementary nucleic acids. Therefore, given the broadest reasonable interpretation of Kobashi's bioidentifiers, they encompass nucleic acids. Third, the teaching of Kobashi is relied upon for the attachment of a biomolecule to a diamond substrate as a modification biomolecule attachment taught by Chrisey. Because both Kobashi and Chrisey et al are concerned with biomolecule attachment to a diamond substrate, it would have been obvious to one skilled to apply the teaching of Kobashi to that of Chrisey et al.

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9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

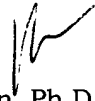
10. No claim is allowed.


11. The examiner's Art Unit has changed from 1655 to 1634. Please address further correspondence to Art Unit 1634.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
October 22, 2002


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600